

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference CWRU-PWO-048	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/US2005/011381	International filing date ( <i>day/month/year</i> ) 01 April 2005 (01.04.2005)	Priority date ( <i>day/month/year</i> ) 01 April 2004 (01.04.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant CASE WESTERN RESERVE UNIVERSITY		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> Box No. I    | Basis of the report   |
| <input type="checkbox"/> Box No. II              | Priority  |
| <input checked="" type="checkbox"/> Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/> Box No. IV              | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI              | Certain documents cited   |
| <input type="checkbox"/> Box No. VII             | Certain defects in the international application  |
| <input checked="" type="checkbox"/> Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 04 October 2006 (04.10.2006)
Facsimile No. +41 22 338 82 70	Authorized officer  Agnes Wittmann-Regis
Form PCT/IB/373 (January 2004)	e-mail: pt06@wipo.int

PCT

To:

see form PCT/ISA/220

27/10

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/US2005/011381

International filing date (day/month/year)  
01.04.2005

Priority date (day/month/year)  
01.04.2004

International Patent Classification (IPC) or both national classification and IPC  
A61K31/409, A61P35/00, A61P35/04, A61P43/00

Applicant  
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For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Authorized Officer

Taylor, G.M.

Telephone No. +49 89 2399-8406



---

**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
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4. Additional comments:

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 12-24

because:

- ☒ the said international application, or the said claims Nos. 12-24 relate to the following subject matter which does not require an international preliminary examination (*specify*):

**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
  - the written form ☐ has not been furnished
  - ☐ does not comply with the standard
  - the computer readable form ☐ has not been furnished
  - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

---

1. Statement

Novelty (N)	Yes: Claims	5, 6, 8-11, 18, 19, 21-24, 28, 29, 31, 32
	No: Claims	1-4, 7, 12-17, 20, 25-27, 30, 33
Inventive step (IS)	Yes: Claims	
	No: Claims	1-33
Industrial applicability (IA)	Yes: Claims	1-11, 25-33
	No: Claims	

2. Citations and explanations

see separate sheet

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**Box No. VIII Certain observations on the international application**

---

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**Cited Documents**

- D1: WO 02/096913 ✓  
D2: EP-A-0 633 024 ✓  
D3: EP-A-0 720 853 ✓  
D4: WO 92/01753 ✓  
D5: US-A-5 358 940 ✓  
D6: WO 95/06688 ✓  
D7: WO 99/23882 ✓  
D8: VOROZHTSOV, G N ET AL: "Phosphonylmethyl phthalocyanine derivatives in preparations for photodynamic therapy" CHEMICAL ABSTRACTS 2002, vol. 136, abstract no. 183942.  
D9: WO 03/037902 ✓  
D10: WAINWRIGHT, M: "Local treatment of viral disease using photodynamic therapy" ✓ INTERNATIONAL JOURNAL OF ANTIMICROBIAL AGENTS 2003, 21, 510-520.

**Section III**

1. Claims 12-24 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Art. 34(4)(a)(I) PCT).

**Section V**

2. Claims 1-4, 7, 12-17, 20, 25-27, 30 and 33 do not meet the requirements of Art. 33(2) PCT because compositions falling within the scope of the present claims are known in the prior art for use in methods of treatment also falling within the scope of the present application. See documents D1-D4, D6, D7 and D8.
3. The novel aspects of the claimed subject-matter cannot be seen as meeting the requirements of Art. 33(3) PCT.

It is clear from the cited prior art that compositions claimed in the present application are useful in the treatment of tumours. Furthermore, topical administration is presented as being a viable, if not preferred, mode of administration (see D2, page 2, lines 8-18 and D3, page 2, lines 5-24).

Moreover, the use of novel salts of known pharmaceuticals cannot be seen as being inventive unless their use results in an advantageous or unexpected effect

not derivable from the prior art.

4. Notwithstanding the above objections, the claimed subject-matter does not meet the requirements of Art. 33(3) PCT over its whole scope.

It is clear from D3 (page 2, lines 20-24) that not all topical formulations of (at least) zinc phthalocyanines are effective in providing significant skin penetration and hence being of use in PDT.

Moreover, the Applicant has only provided data to cover a very small sub-set of the range of compounds claimed.

A reasonable doubt that the underlying technical problem is solved over the whole scope of the claims therefore exists and an inventive step cannot be recognised for the present claims.

5. For the assessment of the present claims 12-24 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

#### **Section VIII**

6. Claim 16 is unclear because it refers to "a pharmaceutical composition of claim 14", whereas claim 14 is directed to a method of treatment.

Similar objections apply to claim 23 in respect of its dependency upon claim 22.

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because:

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**see separate sheet**

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

---

**1. Statement**

Novelty (N)	Yes: Claims	5, 6, 8-11, 18, 19, 21-24, 28, 29, 31, 32
	No: Claims	1-4, 7, 12-17, 20, 25-27, 30, 33
Inventive step (IS)	Yes: Claims	
	No: Claims	1-33
Industrial applicability (IA)	Yes: Claims	1-11, 25-33
	No: Claims	

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**see separate sheet**

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- D2: EP-A-0 633 024
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**Section III**

1. Claims 12-24 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Art. 34(4)(a)(I) PCT).

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2. Claims 1-4, 7, 12-17, 20, 25-27, 30 and 33 do not meet the requirements of Art. 33(2) PCT because compositions falling within the scope of the present claims are known in the prior art for use in methods of treatment also falling within the scope of the present application. See documents D1-D4, D6, D7 and D8.
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It is clear from the cited prior art that compositions claimed in the present application are useful in the treatment of tumours. Furthermore, topical administration is presented as being a viable, if not preferred, mode of administration (see D2, page 2, lines 8-18 and D3, page 2, lines 5-24).

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#### **Section VIII**

6. Claim 16 is unclear because it refers to "a pharmaceutical composition of claim 14", whereas claim 14 is directed to a method of treatment.

Similar objections apply to claim 23 in respect of its dependency upon claim 22.

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	No: Claims	1-4, 7, 12-17, 20, 25-27, 30, 33
Inventive step (IS)	Yes: Claims	
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Industrial applicability (IA)	Yes: Claims	1-11,25-33
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2. Citations and explanations

see separate sheet

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